# Sodium Carbonate
# Interim Registration Review Decision
# Case Number: 4066

## September 2018

Approved by _____

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# I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) *Interim Registration Review Decision* for sodium carbonate and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Initially, case 4066 was known as the Weak Mineral Bases Case (or "Mineral Bases, Weak") and included the chemically similar active ingredients: sodium carbonate (PC Code 073506), potassium carbonate (PC Code 073504), sodium sesquicarbonate (PC Code 073507), and calcium hydroxide (PC Code 075601). Pursuant to 40 CFR Section 155.42(b)(3), calcium hydroxide has since been moved to case 5105 to be assessed with the active ingredient calcium oxide. Since sodium carbonate is the only remaining chemical in the case with registered products, the case name was changed from "Weak Mineral Bases" to "Sodium Carbonate" to reflect that the only chemical to be reviewed under this registration review case is sodium carbonate. Further information and additional registration review documents on sodium carbonate (PC Code 073506) can be found in EPA's public docket (EPA-HQ-OPP-2012-0809) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

Sodium carbonate was first registered in the United States in 1964. The Food and Drug Administration (FDA) assessed the toxicity of carbonates and bicarbonates in 1975 and continues to list sodium carbonate as Generally Recognized as Safe (GRAS). A Reregistration Eligibility Decision (RED) was issued by the Agency for Sodium Carbonate, Weak Mineral Acids in 2006 as a fungicide and for use as a hard surface disinfectant and sanitizer in institutional and residential settings. The Agency concluded that sodium carbonate posed no risks of concern when used according to EPA-approved product labeling. The RED for sodium carbonate is located in docket number EPA-HQ-OPP-2006-0028. After the risk assessments were completed to support the RED, registered uses were expanded in 2005 to include mold, mildew, and fungi remediation on hard surfaces of commercial, industrial, institutional, and residential building and construction materials,

building premises, contents and furnishings, and pre-treatment of building and construction materials; in 2007, registered uses were expanded to include fabric surfaces; and in 2008, registered uses were further expanded to include materials preservative uses that include treated agricultural and mulch films. When each new use was added, the Agency confirmed that the additional uses of sodium carbonate posed no risks of concern.

Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for sodium carbonate in 2012. The following timeline highlights significant events that have occurred during the registration review of sodium carbonate:

- Publication of Sodium Carbonate Preliminary Work Plan (PWP) in December 2012 for a 60-day public comment period that closed on February 12, 2013.

- No comments were received on the PWP. The Final Work Plan (FWP) for sodium carbonate was finalized and published in April 2013. No data were required and the Agency determined that updated risk assessments were not needed to support registration review.

- A Proposed Interim Decision (PID) was issued in May 24, 2018 for a 60-day comment period that closed on July 23, 2018.

- No comments were received on the PID.

Additional information on registration review of sodium carbonate can be found in EPA's public docket, which is accessible at www.regulations.gov in docket number EPA-HQ-OPP-2012-0809.

## II. Scientific Assessment

There are currently three end use products that contain sodium carbonate as an active ingredient. All three of these products are ready to use liquid formulations and they contain 0.95 to 1.0 percent sodium carbonate. Two of these products (EPA Reg. Nos. 4091-23 and 82552-1) are surface disinfectants/sanitizers applied to hard and soft surfaces in a wide variety of medical, commercial and residential areas. The other product (EPA Reg. No. 82552-2) is a materials preservative for building materials, paper products, home furnishings, floor coverings, sporting goods, apparel, plastic films, air filters, cleaning supplies, etc.

### A. Human Health Assessment

EPA did not conduct an updated human health risk assessment for the registration review of sodium carbonate. The most recent human health risk assessment for sodium carbonate was completed in 2007. Comprehensive reviews of the toxicology of sodium carbonate have been conducted by regulatory organizations including the EPA, FDA, and the Food and Agriculture Organization (FAO)/World Health Organization (WHO). In the 2006 Reregistration Eligibility Decision (RED), the Agency reviewed toxicology data, which included unpublished studies submitted to the Agency and published literature, and concluded that the toxicological database for sodium carbonate was

sufficient for reregistration. Based on previous reviews and the currently registered uses, the Agency believed that the toxicological information for sodium carbonate was adequate for the purposes of registration review. There were no endpoints of concern for oral, dermal, or inhalation exposure to sodium carbonate and no evidence of increased susceptibility in a developmental toxicity study[1]; therefore, a quantitative human health risk assessment was not conducted for the RED and not needed for registration review. In the 2013 Final Work Plan (FWP) for the registration review of sodium carbonate, the Agency determined that no additional data or updated risk assessments would be needed.

### 1. Risk Conclusions

Because the data indicate that there are no endpoints of concern for oral, dermal, or inhalation exposure to sodium carbonate and no evidence of increased susceptibility in a developmental toxicity study, the EPA believes that risks to human health from the use of sodium carbonate are expected to be minimal when products are used according to labeled directions.

### 2. Human Incidents

No human incidents resulting from the use of registered antimicrobial products containing sodium carbonate have been reported in OPP's Incident Data System (IDS) between 1992 and July 23, 2018, when the database was last checked.

### 3. Tolerances

There is an exemption from the requirement of a tolerance for sodium carbonate (40 CFR 180.1234). FDA lists sodium carbonate as GRAS when used as a direct food additive substance (21 CFR §184.1742); no limit is placed on the amount of sodium carbonate added to food except current good manufacturing practice.

### 4. Dietary Exposure (Food and Drinking Water)

Products containing sodium carbonate are registered for use as mildewcides, fungicides, and fungistats, sanitizers, and disinfectants on hard surfaces and soft fabric surfaces of commercial, industrial, institutional, residential building and construction materials, and as a material preservative. Products containing sodium carbonate are also registered for use as a pre-treatment on building and construction materials for use in mold remediation and prevention.

Although human dietary exposure via food contact and drinking water to sodium carbonate may occur as a result of the registered uses, there is no risk of concern associated with sodium carbonate because there are no endpoints of toxicological concern.

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[1] Richards, M.B., and W.A. Greg, 1952. The effects of additions of calcium carbonate to the diet of breeding mice. 1. Effects on reproduction and the heart and thymus weights of the weanlings. Brit. J. Nutr. 6:265-280. Cited in Life Sciences Research Office, Federation of American Societies for Experimental Biology (1975). Evaluation of the Health Aspects of Carbonates and Bicarbonates as Food Ingredients. Contract No. FDA 223-75-2004.

### 5. Occupational and Residential Exposure

As stated previously, there are no endpoints of concern for oral, dermal, or inhalation exposure to sodium carbonate. Therefore, a quantitative human health risk assessment of occupational and residential exposures to sodium carbonate was not needed for registration review.

### 6. Aggregate Exposure

An aggregate assessment was not necessary for sodium carbonate because there were no residential or dietary risks identified. In examining aggregate exposure, EPA takes into account the available and reliable information concerning exposures to pesticide residues in food and drinking water, and non-occupational pesticide exposures. Risks associated with these exposures are expected to be minimal based on limited evidence of any subchronic or chronic systemic effects through any route of exposure.

### 7. Cumulative Exposure

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for sodium carbonate. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

## B. Environmental Assessment

The Agency determined a quantitative environmental risk assessment for sodium carbonate was not needed. The antimicrobial use patterns of sodium carbonate (hard surface and fabric sanitizer, disinfectant, and fungicide) are expected to result in minor or insignificant amounts being disposed of down-the-drain as compared to the loading of sodium and carbonates from their non-antimicrobial uses (e.g. water supply softener and as an additive in soaps and detergents). Therefore, these uses are not expected to result in large changes in pH or buffering capacity of surface waters. The registered materials preservatives use is also not expected to result in any significant amounts of sodium carbonate reaching surface waters; additionally, the use of treated agricultural and mulch films is not expected to significantly change the soil pH and alkalinity at use sites.

### 1. Environmental Fate and Exposures

No environmental fate and exposure assessment data were submitted for assessment in support of registration. However, because effluent from waste water treatment plants are treated to appropriate pH limits and dilutions in relation to the natural pH and buffering capacity of the receiving water before being released into the environment (40 CFR §133.102), adverse effects to the aquatic environment, including algae, are not expected to result from the use and disposal of pesticidal products containing sodium carbonate.

### 2. Ecological Effects Assessment

No ecological exposure data were submitted for assessment in support of registration. Based on peer reviewed literature for sodium carbonate, the Agency has concluded that the currently registered uses of this active ingredient should not result in unreasonable adverse effects to the environment. EPA determined that no pollinator exposure and effects data are necessary to make a final registration review decision for sodium carbonate.

### 3. Ecological Incidents

No ecological incidents were reported in OPP's Incident Data System (IDS) for calcium carbonate between 1994 and July 23, 2018, when the database was last checked.

## C. Endangered Species Assessment

Based on low hazard and exposure, there is no reasonable expectation for the registered use of sodium carbonate to cause direct or indirect adverse effects to threatened and endangered species. No adverse modification of any designated critical habitat for such species is expected from the use of sodium carbonate. The Agency has made a "no effect" (NE) determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required at this time.

## D. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for sodium carbonate, EPA did not identify endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), sodium carbonate is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go

through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013[2] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Sodium carbonate is not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[3]

In this interim decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of sodium carbonate. Before completing this registration review, the agency will make an EDSP FFDCA section 408(p) determination.

## III. Interim Registration Review Decision

## A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing the *Sodium Carbonate Interim Registration Review Decision*. The Agency's interim decision is that no additional data or labeling changes are needed for products containing sodium carbonate. This includes a determination that no pollinator exposure and effects data are necessary to make a final registration review decision for sodium carbonate. In addition, sodium carbonate is not expected to have direct or indirect adverse effects to non-listed and listed species or to adversely modify any designated critical habitat for such species. The Agency has made a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species. This interim decision does not cover the EDSP component of this registration review case, and a final registration review decision for the sodium carbonate case will depend upon the result of an EDSP FFDCA section 408(p) determination.

[2] See http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.

[3] http://www.epa.gov/endo/

# IV. Next Steps

## A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing the *Sodium Carbonate Interim Registration Review Decision*. The Agency has made a "no effect" determination under ESA for sodium carbonate and a final registration review decision for the sodium carbonate case will depend upon the result of an EDSP FFDCA section 408(p) determination.

## B. Implementation of Mitigation Measures

There are no risk mitigation measures or label amendments included in this Interim Decision.